Outcomes after a decade of laparoscopic giant paraesophageal hernia repair

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Objective: Laparoscopic repair of giant paraesophageal hernia is a complex operation requiring significant laparoscopic expertise. Our objective was to compare our current approach and outcomes for laparoscopic repair of giant paraesophageal hernia with our previous experience.

Methods: A retrospective review of patients undergoing nonemergency laparoscopic repair of giant paraesophageal hernia, stratified by early versus current era (January 1997–June 2003 and July 2003–June 2008), was performed. We evaluated clinical outcomes, barium esophagogram, and quality of life.

Results: Laparoscopic repair of giant paraesophageal hernia was performed in 662 patients (median age 70 years, range 19–92 years) with a median percentage of herniated stomach of 70% (range 30%–100%). With time, use of Collis gastroplasty decreased (86% to 53%), as did crural mesh reinforcement (17% to 12%). Current era patients were 50% more likely to have a Charlson comorbidity index score greater than 3. Thirty-day mortality was 1.7% (11/662). Mortality and complication rates were stable with time, despite increasing comorbid disease in current era. Postoperative gastroesophageal reflux disease health-related quality of life scores were available for 489 patients (30-month median follow-up), with good to excellent results in 90% (438/489). Radiographic recurrence (15.7%) was not associated with symptom recurrence. Reoperation occurred in 3.2% (21/662).

Conclusions: With time, we have obtained significant minimally invasive experience and refined our approach to laparoscopic repair of giant paraesophageal hernia. Perioperative morbidity and mortality remain low, despite increased comorbid disease in the current era. Laparoscopic repair provided excellent patient satisfaction and symptom improvement, even with small radiographic recurrences. Reoperation rates were comparable to the best open series. (J Thorac Cardiovasc Surg 2010;139:395-404)

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Supplemental material is available online.

Surgical repair of giant paraesophageal hernia (GPEH) is a complex operation, and the laparoscopic approach requires advanced laparoscopic expertise. With time, the feasibility and safety of a laparoscopic approach to GPEH repair have been established[1-3]; however, there is still considerable debate regarding the optimal approach to operative repair, use of routine mesh reinforcement of the hiatus, the need for an esophageal lengthening procedure, and routine fundoplication. Attempts to address these questions have been limited by the small numbers of patients reported in most series.

During the past decade, we have refined the operation and acquired significant experience in advanced laparoscopic techniques. This study was designed to achieve the following aims: (1) to describe the perioperative morbidity and mortality associated with the laparoscopic approach and to determine whether these rates have changed during the period of study; (2) to evaluate patient and operative factors contributing to increased risk of perioperative adverse outcomes; (3) to assess symptom relief, quality of life, radiographic and symptomatic recurrence, and the need for reoperation for symptomatic recurrent hernia during follow-up; and (4) to identify potential risk factors for radiographic recurrence and the need for reoperation.

MATERIALS AND METHODS

Patient Selection and Stratification

Patients undergoing elective or urgent laparoscopic repair of GPEH (defined as >30% of the stomach herniated into the mediastinum) from January 1, 1997, to June 30, 2008, were included. During this period, 739 consecutive patients underwent operative repair of GPEH. For this analysis, patients were excluded if they required emergency surgery (n = 13), had a planned open operation (n = 13), or had previous antireflux surgery (n = 51). Patients requiring hospitalization for hernia-associated symptoms and repaired urgently during the same admission were included in this analysis (n = 106, 16%). This retrospective study was approved by our institutional review board.

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Abbreviations and Acronyms

BMI = body mass index
CCI = Charlson comorbidity index
CI = confidence interval
GERD-HRQoL = Gastroesophageal Reflux Disease Health Related Quality of Life
GPEH = giant paraesophageal hernia
IQR = interquartile range
LOS = length of stay
OR = odds ratio
SF-36 = Medical Outcomes Study Short Form-36 Health Survey

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Patient Demographic Characteristics and Operative Techniques

Attempted elective or urgent laparoscopic repair of GPEH was performed in 662 consecutive patients. Conversion to an open procedure was necessary in 10 cases (1.5%) for bleeding (n = 3), gastric perforation or serosal tear (n = 2), adhesions (n = 3), or inability to reduce the hernia laparoscopically (n = 2). Most patients were female (75%, median age 70 years, interquartile range [IQR] 19–92 years). Body mass index (BMI) of at least 35 kg/m^2 was documented in 15% of patients. Preoperative history of anemia or hematocrit lower than 37% was found in 41% of patients (n = 271/654). Age-adjusted Charlson comorbidity index (CCI) score was at least 3 for 49% of patients.

Operative Approach

The operative approach to laparoscopic GPEH repair continues to be a work in progress (details online in Appendix E1.) In this series, esophageal lengthening (Collis gastroplasty) was used in 63%, mesh cruroplasty in 13%, and fundoplication (floppy Nissen or partial fundoplasty) in 98% (Table 1). Operations were performed by 13 thoracic surgeons at the University of Pittsburgh Medical Center. Two senior surgeons, J.D.L. and R.J.L., performed 56% (n = 372) and 17% (n = 114), respectively. Under senior supervision, junior surgeons with advanced minimally invasive foregut surgical training (minimum of 25 laparoscopic GPEH repairs) performed the remaining operations. Independent operation required a minimum of 10 successful proctored cases.

Database

With a standardized outcome protocol, data on patients undergoing repair of GPEH were collected retrospectively by trained research personnel and entered into a computerized surgical outcomes database. Data included standard observer-recorded measures, preoperative symptoms, laboratory and radiographic studies, operative details, length of stay (LOS), perioperative mortality, and postoperative adverse outcomes (in-hospital and 30-day outcomes).

Symptom assessment questionnaire, barium esophagogram, the Gastroesophageal Reflux Disease Health Related Quality of Life (GERD-HRQoL) instrument,[4,5] and the Medical Outcomes Study Short Form-36 Health Survey (SF-36)[6] were obtained as described previously.[7] The GERD-HRQoL and SF-36 questionnaires were administered in the clinic by trained clinic personnel. Raw GERD-HRQoL scores were converted to categoric variables as follows: excellent for 0 to 5, good for 6 to 10, fair for 11 to 15, and poor for 16 or greater.[8] Radiographic recurrence was considered present if more than 10% or 2 cm of the stomach was located above the level of the diaphragm on barium esophagraphy.[7,9] All subsequent esophageal operations were recorded, including reoperation for recurrence (n = 21), conversion to Roux-en-Y procedure for obesity (n = 3), and esophagectomy for cancer (n = 3).

Statistical Analysis

Statistical analysis was performed with STATA SE 10.0 software (StataCorp LP, College Station, Tex). Primary outcome variables were as follows: (1) perioperative mortality (in-hospital or 30-day mortality) and (2) major morbidity (including pneumonia, perioperative hernia recurrence, postoperative leak, pulmonary embolism, need for reoperation, and hospital readmission) and LOS. Secondary outcome measures were as follows: (1) reoperation for recurrent hernia, (2) radiographic recurrence according to barium esophagography, and (3) patient-reported outcomes.

Perioperative Morbidity and Mortality Associated With Laparoscopic Approach

Data were summarized with frequencies and percentages for categoric variables and median with IQR for continuous variables for the entire cohort and then stratified by date of surgery (early January 1, 1997–June 30, 2003, current July 1, 2003–June 30, 2008). Fisher's Exact Test, χ^2 test, and Student *t* test, accounting for unequal variance, were used to describe differences between groups. To determine factors associated with increased risk for death or major adverse outcomes, crude and adjusted analyses were performed with univariate and multivariate logistic regression. Preoperative and current (most recent) patient-reported outcomes measures were compared with the McNemar χ^2 test for differences in proportions of paired outcomes. With logistic regression, the odds ratios (ORs) for radiographic recurrence, reoperation for recurrence, and recurrent symptoms associated with the finding of recurrent hiatal hernia on barium esophagography were determined. Two-sample Wilcoxon rank-sum (Mann–Whitney) test for differences between means was used to calculate the differences in SF-36 summary scores and GERD-HRQoL composite score, stratified by radiographic hernia recurrence.

Missing Data

When clear documentation of the presence or absence of a symptom was not found in retrospective chart review, the data were considered missing. Recognizing that missing data may introduce bias into the analysis, patient factors associated with the probability of data being missing were evaluated with Fisher's Exact Test and univariate logistic regression.

RESULTS

Perioperative Morbidity and Mortality After Laparoscopic GPEH Repair

Major adverse outcomes included pneumonia (n = 29/653, 4%), congestive heart failure (n = 17/654, 2.6%), pulmonary embolism (n = 22/653, 3.4%), postoperative leak (n = 16/653, 2.5%), perioperative hernia recurrence (n = 5/652, 0.8%), need for reintubation (n = 17/655, 2.6%), acute renal failure (n = 6/656, 0.9%), cerebrovascular accident (n = 4/653, 0.6%), and myocardial infarction (n = 6/653, 0.9%). Most postoperative leaks occurred in patients who underwent Collis gastroplasty (n = 14/16, 88%). There were 11 postoperative deaths (n = 11/662, 1.7%). Reoperation within 30 days was performed in 32 cases (n = 32/650, 4.9%) for postoperative leak (n = 11), recurrent hernia (n = 3), visceral injury

TABLE 1. Cohort analysis of early (January 1, 1997–June 30, 2003) versus current (July 1, 2003–June 30, 2008) surgical experience

	Overall (n = 662)	Early (n = 202)	Current (n = 460)	Crude odds ratio*	*P* value
Patient demographic data					
Male	167 (25%)	57 (28%)	110 (24%)	0.8 (0.5–1.2)	.24
Age ≥70 y	336 (51%)	101 (50%)	235 (51%)	1.0 (0.8–1.5)†	.8
Obese (body mass index ≥35 kg/m^2, n = 620)	92 (15%)	25 (13%)	67 (15%)	1.2 (0.7–1.9)	.6
Charlson comorbidity index ≥3† (n = 660)	326 (49%)	85 (42%)	241 (53%)	1.5 (1.1–2.1)	.01
Preoperative hernia size (%)‡					
30%–49%	280 (42%)	78 (39%)	202 (44%)	Referent	.12
50%–74%	87 (13%)	23 (11%)	64 (14%)	1.1 (0.6–1.9)	
75%–99%	148 (22%)	52 (26%)	96 (21%)	0.7 (0.5–1.1)	
Intrathoracic stomach	147 (22%)	49 (24%)	98 (21%)	0.8 (0.5–1.2)	
Preoperative pulmonary disease	163 (25%)	38 (19%)	125 (27%)	1.6 (1.1–2.4)	.02
History of ever smoking (n = 650)	251 (39%)	70 (36%)	181 (40%)	1.2 (0.8–1.7)	.32
Preoperative symptoms					
Chest or abdominal pain (n = 655)	353 (54%)	102 (51%)	251 (55%)	1.2 (0.8–1.7)	.33
Heartburn (n = 650)	431 (66%)	118 (59%)	313 (70%)	1.6 (1.1–2.3)	.007
Dysphagia (n = 648)	280 (43%)	76 (38%)	204 (45%)	1.3 (0.96–1.9)	.09
Difficulty swallowing (n = 637)					
Hard solids	204 (32%)	54 (28%)	150 (34%)	1.4 (0.9–2.0)§	.29
Soft solids	42 (7%)	10 (5%)	32 (7%)	1.6 (0.8–3.4)§	
Liquids	21 (3%)	8 (4%)	13 (3%)	0.8 (0.3–2.0)	
Regurgitation (n = 655)	388 (59%)	110 (55%)	278 (61%)	1.3 (0.9–1.8)	.12
Dyspnea (n = 650)	273 (42%)	72 (36%)	201 (45%)	1.4 (1.0–2.0)	.03
Bloating (n = 634)	195 (31%)	57 (29%)	138 (32%)	1.2 (0.8–1.7)	.4
Operative details					
Esophageal lengthening procedure (n = 647)	408 (63%)	171 (86%)	237 (53%)	0.2 (0.1–0.3)	<.0001
Fundoplication	647 (98%)	198 (98%)	449 (98%)	0.8 (0.3–2.6)	.74
Mesh reinforcement of crura	88 (13%)	35 (17%)	53 (12%)	0.6 (0.4–0.99)	.04
Conversion to open operation	10 (1.5%)	2 (1%)	8 (1.7%)	1.8 (0.4–8.4)	.47
Operative time >260 min§ (n = 630)	182 (29%)	85 (42%)	97 (21%)	0.4 (0.3–0.5)	<.0001

Data are presented as numbers of patients with percentages in parentheses. *Odds ratio represents the odds of each variable in the current cohort compared to the early cohort; 95% confidence interval is given in parentheses. †Charlson comorbidity index adjusted for age. ‡Percentage of stomach within the mediastinum determined by barium esophagography, preoperative endoscopy, or intraoperative description. Complete intrathoracic stomach was defined as the entire stomach, including the antrum, herniated into the mediastinum. §Operative time longer than 260 minutes represents the 75th percentile for operative time for the entire cohort.

(n = 2), wound infection requiring incision and drainage (n = 2), bleeding (n = 2), enteral access for nutrition (n = 6), obstructing fundoplication (n = 1), small-bowel obstruction (n = 1), empyema (n = 1), retained foreign body (n = 1), paraesophageal hematoma (n = 1), and incisional hernia (n = 1).

Laparoscopic Repair of GPEH in the Current Era

During the study period, significant shifts in the patient cohort undergoing nonemergency laparoscopic repair, the approach to operation, and operative details have occurred (Table 1). Adverse outcomes in the postoperative period did not differ significantly between the eras, despite the increased comorbid disease burden in the current cohort (data not shown). Current era patients were 60% less likely to undergo reoperation in the immediate postoperative period (OR, 0.4; 95% confidence interval [CI], 0.2–0.9) but were 2.3 times more likely to require admission to the intensive care unit than in the early era (OR, 2.3; 95% CI, 1.5–3.4). This finding reflects the increased prevalence of comorbid diseases in the current patient population. Median postoperative LOS was 3 days (IQR, 2–5 days) and did not differ significantly between the eras (early era LOS, 3 days; IQR, 2–5 days, vs current era LOS, 4 days; IQR, 2–5 days; $P = .62$). The 7.5% need for hospital readmission after discharge (n = 15/201) in the early era was similar to 8% (37/458) in the current era ($P = .9$), and postoperative mortalities were similar between the eras (n = 2/202, 1%, vs n = 9/460, 2%, $P = .52$). The most common reason for readmission was thromboembolic complication (n = 6/52, 11.5%).

Factors That May Contribute to Increased Odds of Adverse Outcome

Postoperative mortality. All postoperative deaths were of patients with 1 or more of the following characteristics: age of at least 70 years, BMI of at least 35 kg/m^2, and age-adjusted CCI of at least 3. Mortality at 30 days increased

significantly with age (0% for ages <60 years and 60–69 years, 0.9% for ages 70–79 years, 7.8% for ages ≥80 years, $P < .001$). Postoperative mortality was also associated with urgency of operation. Patients admitted electively for operative repair had a postoperative mortality of 0.5% (n = 3/556) versus 7.5% for patients undergoing urgent repair (n = 8/106).

Major nonfatal adverse outcomes. In multivariate analysis, patients at least 70 years old had a 67% increase (OR, 1.67; 95% CI, 1.1–2.7) in the odds of major nonfatal adverse outcomes relative to those younger than 70 years. Those with age-adjusted CCI scores of at least 3 had a 66% increase (OR, 1.66; 95% CI, 1.1–2.6) in odds of major nonfatal adverse outcome. Odds of postoperative leak were increased 3.8-fold (OR, 3.82; 95% CI, 1.2–12.7) for patients with BMI of at least 35 kg/m^2.

Postoperative LOS. Patients with CCI scores of at least 3 had a 2.7-fold increased odds of a long hospital stay (defined as ≥5 days, OR, 2.7; 95% CI, 1.9–3.8) relative to patients with a CCI score lower than 3. There was a trend toward increased odds of a long hospital stay in the current era (OR, 1.4; 95% CI, 0.96–2.0; $P = .08$) relative to the early era, which disappeared after controlling for comorbidities (OR, 1.3 for LOS ≥5 days in current era; 95% CI, 0.86–1.8; $P = .24$).

Symptom Relief and Quality of Life

Recent symptom follow-up was available for 74% of patients (n = 492/662). Median time to follow-up was 30 months (IQR 17–56 months). There were 170 patients without symptom follow-up (74 deceased and the remaining 96 declining or unavailable for follow-up). Symptom follow-up, validated GERD-HRQoL, and SF-36 were more likely to be missing if patients were at least 80 years old ($P = .02$, $P < .001$, and $P < .001$, respectively) or had a CCI score of 3 or greater ($P = .01$, $P = .01$, and $P = .001$, respectively). Early era of surgery was significantly associated with missing GERD-HRQoL ($P = .001$) and SF-36 ($P = .002$) measures.

Symptomatic relief after laparoscopic GPEH repair. Overall, patients had significant relief of preoperative complaints (Table 2). The proportions of patients reporting dysphagia, heartburn, regurgitation, chest or abdominal pain, shortness of breath, and aspiration were significantly reduced at current follow-up relative to preoperative levels. The proportion of patients reporting postprandial bloating, however, was unchanged. Of patients reporting postprandial bloating before the operation, 33% had persistent symptoms (n = 47/144). In addition, 29% of patients without preoperative bloating (n = 97/337) reported this symptom at most recent follow-up.

Symptoms and association with radiographic recurrence. There were no differences in rates of symptoms between patients with radiographically documented recurrence and those without radiographic recurrence. Radiographic recurrence was not associated with increased odds of recurrent symptoms (Table 3).

Patient satisfaction, GERD-HRQoL, and SF-36. GERD-HRQoL questionnaires were completed by 489 of 662 patients (74%) at a median of 30 months from initial operation (IQR, 17–56 months). According to the GERD-HRQoL satisfaction scale, patient satisfaction with surgery and current symptoms was high (Table 4). Radiographic recurrence did not have a significant impact on patient-reported satisfaction ($P = .79$) or patient-reported reflux-related quality of life and did not necessitate reoperation in most cases.

Finally, overall patient satisfaction was assessed with the SF-36 instrument. A complete SF-36 was available for analysis in 476 of 662 cases at a median time from initial operation of 30 months (IQR, 17–56 months; Table 4).

Radiographic and Symptomatic Recurrence and Need for Reoperation

Long-term radiographic recurrence and need for reoperation. Postoperative barium esophagograms were available for 92% of patients (n = 607/662). For 67% of patients (n = 445/662), the esophagogram was obtained 3 months or longer after operation. Lack of a barium esophagogram obtained 3 months or longer after operation was significantly associated with age of at least 80 years at time of operation ($P = .04$) but not with sex, CCI, BMI, or era of operation. Median time to most recent esophagogram was 25 months (IQR, 12–46 months). Recurrent hiatal hernia was identified in 70 of 445 patients (15.7%) at a median of 22 months (IQR, 11–39 months). Most radiographic recurrences were small (between 11% and 20% reherniation of the stomach or wrap). Radiographic recurrence and significant symptoms leading to a decision to reoperate were present in 3.2% of patients (n = 21/662) at a median follow-up of 25 months (IQR, 17–43 months), with the decision to reoperate driven primarily by the degree of clinical symptoms.

Risk factors for radiographic recurrence and need for reoperation for recurrence. Age younger than 70 at initial operation was associated with significantly increased odds of radiographic recurrence. Age younger than 70 at initial operation, BMI of at least 35 kg/m^2, and mesh cruroplasty at initial operation were associated with an increased odds of need for reoperation in crude and adjusted analyses (Table 5).

DISCUSSION

With this single-institution, decade-long series of 662 patients, we have demonstrated that laparoscopic GPEH repair is feasible, is safe, and provides excellent patient satisfaction and symptom resolution despite an increase in patient comorbid conditions during the study period. Laparoscopic repair of GPEH was successfully accomplished in 98.5% of cases, with a postoperative mortality of 1.7%

TABLE 2. Paired analysis of the relationship between preoperative and current symptoms

	Symptom present preoperatively?				
Current symptom	**Yes**	**No**	**Difference in proportion***	**Odds ratio†**	***P* value‡**
Dysphagia					
Yes	76	55	–0.20 (–0.25 to –0.14)	0.34 (0.25–0.47)	<.0001
No	160	246			
Heartburn					
Yes	100	27	–0.44 (–0.49 to –0.39)	0.1 (0.07–0.15)	<.0001
No	261	138			
Regurgitation					
Yes	28	20	–0.48 (–0.53 to –0.43)	0.08 (0.05–0.12)	<.0001
No	261	193			
Chest or abdominal pain					
Yes	34	30	–0.42 (–0.47 to –0.36)	0.13 (0.09–0.19)	<.0001
No	228	183			
Postprandial bloating					
Yes	47	97	–0.02 (–0.08 to 0.04)	0.92 (0.69–1.2)	.53
No	106	240			
Aspiration					
Yes	2	12	–0.09 (–0.12 to –0.05)	0.24 (0.11–0.45)	<.0001
No	51	387			
Shortness of breath					
Yes	31	29	–0.29 (–0.34 to –0.23)	0.18 (0.12–0.27)	<.0001
No	163	243			
Proton pump inhibitors					
Yes	161	31	–0.41 (–0.46 to –0.36)	0.12 (0.08–0.18)	<.0001
No	249	89			

*Difference in proportion is given with 95% confidence interval in parentheses. †Odds ratio represents likelihood of having a symptom currently if it was present preoperatively; 95% confidence interval is given in parentheses. ‡McNemar χ^2 test for analysis of paired variables.

and major morbidity rate of 19%. Thromboembolic complications were a significant source of postoperative morbidity, despite routine use of antithrombotic compression stockings and subcutaneous heparin. Patient factors that were predictive of increased risk of postoperative death and significant major adverse events were age of at least 70 years, BMI of at least 35 kg/m^2, CCI score of at least 3, and urgent operation. Symptom relief after laparoscopic repair was excellent, with 89% of patients expressing satisfaction with the surgical result at 30 months' median clinical follow-up. Importantly, patients with a limited radiographic recurrence were as satisfied with surgery as those with no radiographic recurrence and reported similar GERD-HRQoL outcomes.

When the current era of operation (July 1, 2003–June 30, 2008) was compared with the early era (January 1, 1997–June 30, 2003), patients in the current era were 50% more likely to have significant age-adjusted comorbidities and 60% more likely to have an underlying pulmonary disease. Despite this, the risk of adverse outcome in the current era was the same as in the early era. Operative time and need for reoperation in the immediate postoperative period were significantly less in the current era, reflecting the experience of the surgical team, ongoing efforts to refine the operative approach, and improvements in perioperative patient care.

The only patient characteristic that was associated with risks of radiographic recurrence and reoperation on multivariate analysis was age younger than 70 years at initial operation. Such an association with younger age has not been previously described, but a possible hypothesis for this observation is that younger patients are healthier and more active, thereby exerting greater stress on the hiatal repair. This may be a subpopulation in which routine crural reinforcement with mesh can lead to improved long-term durability of the repair. Further studies are needed to confirm this association and test this hypothesis.

Laparoscopic Versus Open Repair

The operative outcomes, long-term symptomatic relief, and freedom from radiographic recurrence after laparoscopic repair of GPEH reported here are similar to the outcomes for open repair reported in the literature. Our operative mortality of 1.7% compares quite well with mortalities of 0% to 3.7% that have been reported.[10-12] Interestingly, we found that the operative mortality for elective repair was significantly lower than that for urgent repair (0.5% vs 7.5%), which contradicts recent studies[13] suggesting that mortalities for elective and emergency repairs are not substantially different. In our series, elective repairs in the hands of experienced surgeons had significantly better outcomes than did urgent repairs by the same surgeons.

TABLE 3. Comparison of current symptoms between patients with recurrent hernia according to barium esophagography and those without recurrent hernia

Current symptom	Radiographic recurrence?* Yes	No	*P* value†	Crude odds ratio‡
Dysphagia (n = 380)				
Yes (n = 94, 25%)	15	79	.13	1.75 (0.89–3.5)
No (n = 286, 75%)	28	258		
Heartburn (n = 373)				
Yes (n = 101, 27%)	11	90	>.999	0.92 (0.44–1.9)
No (n = 272, 73%)	32	240		
Regurgitation (n = 350)				
Yes (n = 36, 10%)	6	30	.28	1.65 (0.64–4.3)
No (n = 314, 90%)	34	280		
Chest or abdominal pain (n = 330)				
Yes (n = 46, 14%)	7	39	.31	1.58 (0.65–3.9)
No (n = 284, 86%)	29	255		
Postprandial bloating (n = 408)				
Yes (n = 122, 30%)	16	106	.50	1.24 (0.65–2.67)
No (n = 286, 70%)	31	255		
Aspiration (n = 318)				
Yes (n = 11, 4%)	1	10	1.00	0.92 (0.11–7.5)
No (n = 307, 96%)	30	277		
Shortness of breath (n = 326)				
Yes (n = 48, 15%)	7	41	.31	1.59 (0.65–3.9)
No (n = 278, 85%)	27	251		
Proton pump inhibitors (n = 369)				
Yes (n = 145, 39%)	16	129	1.00	0.99 (0.51–1.9)
No (n = 224, 61%)	25	199		

*Analysis includes only those patients with barium esophagogram at least 3 months after initial operation and current symptoms. If patients required reoperation (including for recurrent hernia, treatment of obesity, or esophageal cancer), symptom follow-up was censored to the most recent symptoms before reoperation. †Fisher's Exact Test for differences in symptoms between patients with and without radiographic recurrence. ‡For odds ratio, 95% confidence interval is given in parentheses.

TABLE 4. Analysis of the impact of radiographic recurrence on gastroesophageal reflux disease–related and overall patient health status at current clinical follow-up

	All patients	Radiographic recurrence* Yes	No	*P* value
Satisfied with surgery and current symptoms				
	n = 493	n = 41	n = 314	
Yes	440 (89%)	37 (90%)	284 (90%)	.79†
No	53 (11%)	4 (10%)	30 (10%)	
Gastroesophageal Reflux Disease Health Related Quality of Life‡				
	n = 489	n = 41	n = 312	
Median and IQR	1 (0-4)	1 (0-4)	2 (0-6)	.33§
Excellent to good	438 (90%)	36 (88%)	279 (89%)	.79†
Fair to poor	51 (10%)	5 (12%)	33 (11%)	
Short-form 36 Health Survey (median and IQR)				
	n = 476	n = 40	n = 304	
Physical Component Summary	51 (40-57)	54 (48-57)	51 (40-57)	.12§
Mental Component Summary	53 (47-56)	53 (49-56)	53 (49-56)	62§

IQR, Interquartile range. *Includes only patients with current barium esophagogram and Short-form 36 Health Survey score. Results for patients requiring reoperation were censored at the date of reoperation. †Two-sample Wilcoxon rank-sum (Mann-Whitney) test ‡Scale as follows: excellent (score 0–5), good (score 6–10), fair (score 11–15), poor (score >15). §Fisher's Exact Test for independence.

This observation warrants further study to describe this association more clearly.

Our radiographic recurrence and symptom outcomes also compare favorably with the outcomes reported for open repair and contrast with the high rates of radiographic recurrence published in some series of laparoscopic repair.[7,10,14-16] Hashemi and colleagues[10] in 2000 were among the first to publish a high rate of radiographic recurrence for patients undergoing laparoscopic repair (42% radiographic recurrence rate in 27 patients, median time to barium esophagogram 17 months). This sharply contrasted with the 15% radiographic recurrence rate in the open group (median time to barium esophagogram 35 months). Symptomatic relief was also worse in their laparoscopic group; 77% of patients reported a good to excellent outcome versus 88% in their open group. These results emphasize the need for surgeons to assess their ongoing clinical outcomes and strive for superior outcomes with the surgical approach that works best for their group. In our center, extensive minimally invasive surgical experience and good to excellent results in close to 90% of our patients undergoing laparoscopic repair of GPEH has led to our adoption of this approach in preference to the open approach.

Ongoing Debate Regarding Mesh Cruroplasty and Esophageal Lengthening

The roles of esophageal lengthening and mesh cruroplasty in repair of GPEH continue to be debated among surgeons, and a clear answer does not exist.[7,17-21] Hiatal herniation is associated with two distinct processes: axial tension caused by proximal migration of the gastroesophageal junction in the setting of acquired short esophagus and radial tension exerted on the hiatal orifice as the hernia enlarges.[22] The goal of esophageal lengthening is to eliminate the axial tension exerted on the hiatus by creating an adequate length of intra-abdominal neoesophagus. The goal of mesh cruroplasty is to strengthen the ability of the hiatus to resist radial tension created by the pressure differential between the abdomen and thorax. As such, use of either esophageal lengthening or mesh cruroplasty is an intraoperative decision that should be made after optimal surgical mobilization of the esophagus and diaphragm. The surgeon then determines the best repair for the patient. The optimal repair may require

TABLE 5. Analysis of preoperative risk factors and operative techniques and the risk of reoperation and radiographic recurrence at any time after operation

	Radiographic recurrence (n = 445)*			Reoperation for recurrent hernia/symptoms		
	No.	Crude OR†	*P* value	No.	Crude OR†	*P* value
Overall‡	70/445 (15.7%)			21/662 (3.2%)		
Age at initial operation						
<70 y	44/235 (19%)	Referent	.07	16/326 (4.9%)	Referent	.01
≥70 y	26/210 (12%)	0.61 (0.36–1.04)		5/336 (1.5%)	0.29 (0.11–0.81)	
Age-adjusted Charlson comorbidity index						
<3 (n = 334)	42/239 (18%)	Referent	.25	12/334 (3.6%)	Referent	.53
≥3 (n = 328)	28/206 (14%)	0.74 (0.44–1.24)		9/326 (2.7%)	0.76 (0.3–1.8)	
Body mass index						
<35 kg/m^2	50/351 (14%)	Referent	.09	15/528 (2.8%)	Referent	.07
≥35 kg/m^2	15/67 (22%)	1.74 (0.91–3.3)		6/92 (6.5%)	2.4 (0.9–6.3)	
Preoperative pulmonary disease						
None (n = 499)	51/337 (15%)	Referent	.54	13/499 (2.6%)	Referent	.15
Present (n = 163)	19/108 (18%)	1.2 (0.67–2.13)		8/163 (4.9%)	1.93 (0.78–4.75)	
Preoperative hernia size§						
30%–49%	28/189 (15%)	Referent	.60‖	12/280 (4.3%)	Referent	.1
50%–74%	10/67 (15%)	1.0 (0.46–2.2)		4/87 (4.6%)	1.1 (0.3–3.4)	
75%–99%	17/99 (17%)	1.2 (0.6–2.3)		2/148 (1.4%)	0.3 (0.1–1.4)	
Complete intrathoracic stomach	15/90 (17%)	1.2 (0.58–2.3)		3/147 (2.0%)	0.5 (0.1–1.7)	
Type of fundoplication¶						
Partial	16/100 (16%)	Referent	.89	6/135 (4.4%)	Referent	.37
Circumferential	52/337 (15%)	0.96 (0.52–1.77)		15/512 (2.9%)	0.65 (0.25–1.7)	
Esophageal lengthening						
None (n = 212)	24/165 (15%)	Referent	.65	10/239 (4.2%)	Referent	.3
Collis gastroplasty (n = 383)	44/272 (16%)	1.13 (0.66–1.94)		11/408 (2.7%)	0.63 (0.27–1.5)	
Mesh cruroplasty						
None (n = 574)	58/387 (15%)	Referent	.27	13/574 (2.3%)	Referent	.0007
Mesh (n = 88)	12/58 (21%)	1.48 (0.74–2.97)		8/88 (9.1%)	4.3 (1.7–10.8)	
Operative time						
<260 min	46/331 (14%)	Referent	.07	14/480 (2.9%)	Referent	.54
≥260 min	24/114 (21%)	1.65 (0.95–2.86)		7/182 (3.9%)	1.3 (0.5–3.4)	

*Analysis includes only those patients with barium esophagogram †For odds ratio, 95% confidence interval is given in parentheses. ‡Analysis was also performed for preoperative pulmonary function testing, history of peptic ulcer disease or diabetes, postoperative complications (leak, pneumonia, acute renal failure, perioperative hernia recurrence, any need for reoperation in the perioperative period), and no association with risk for reoperation and radiographic recurrence was identified. §Percentage of stomach within the mediastinum determined by barium esophagography, preoperative endoscopy, or intraoperative description. Complete intrathoracic stomach was defined as the entire stomach, including the antrum, herniated into the mediastinum. ‖*P* value for score test for trend of odds. ¶Two patients with recurrence did not receive a fundoplication at the initial operation (1 gastropexy and 1 Roux-en-Y gastric bypass).

both esophageal lengthening and mesh cruroplasty, one but not the other, or neither.

In our series, use of mesh cruroplasty in most cases was not necessary in the opinion of the surgeon. We believe that two factors are critical to the success of primary crural reapproximation: (1) maintenance of the peritoneal lining over the crura, and (2) complete division of all attachments from the diaphragm to the stomach and spleen. This allows free mobility of the left limb of the crus and facilitates reapproximation without tension. In our experience, we accomplished these ends most of the time, and mesh was only required in 13% of cases when the overlying peritoneum had been compromised, leading to exposed muscle fibers of poor integrity, or the hiatal opening could not be closed without undue tension. The finding in our series that mesh cruroplasty was associated with significantly increased odds of reoperation for recurrence with time and was not protective against radiographic recurrence reflects the fact that we use mesh only when the crural closure is compromised. Similarly, this finding may also indicate that the type of mesh and the technical aspects of the cruroplasty are still in evolution and that the ideal approach has not been determined.

Conversely, Collis gastroplasty for esophageal lengthening was used in 63% of patients in this series. Most of our patients had type III paraesophageal hernia. Restoring adequate length to the intra-abdominal esophagus returns the gastroesophageal junction to the abdomen and releases the axial tension created by the shortened esophagus, thereby minimizing the axial forces exerted on the hiatal repair.

Although the use of esophageal lengthening did decreased with time in our series, in our opinion, this is because of the increased experience and success of extended mediastinal mobilization. For some patients with mild to moderate shortening, extended mobilization may obviate the need for an esophageal lengthening procedure or at least may limit the length of the Collis gastroplasty to a shorter segment. This is clearly an important component of the repair, and every effort should be made to strive for adequate esophageal length with laparoscopic esophageal mobilization to the maximal degree possible before determining whether a Collis gastroplasty is indicated.

Study Limitations

This study has several strengths and limitations. Long-term follow-up of this patient population can be difficult to obtain because of the extremes of age and also the costs of maintaining a clinical outcomes research team. We present midterm validated patient-reported outcomes for 74% of patients at a median follow-up of 30 months. Radiographic follow-up at least 3 months after operation was available for 67% of patients at a median follow-up of 25 months. Although these numbers are comparable to other series,[10,14,15,23,24] a concerted effort has been made during the past 2 years to improve our longitudinal care for these patients, and clinical pathways have been instituted at our center to provide routine and standardized follow-up. Despite these measures, serial time points were not available for most patients, limiting assessment of the time course for radiographic or symptom recurrence.

The degree of missing data for the outcomes measured in this study is also a limitation of the study. When factors associated with missing data were analyzed, we found that patients who were 80 years or older at the time of operation, those with significant comorbid illness, and those operated on during the early era were more likely to be missing follow-up symptom questionnaires and validated quality of life studies. Octogenarians were also more likely to be missing a barium esophagogram obtained at least 3 months after the operation. This degree of missing data introduces bias into the analysis that must be taken into consideration. For example, the percentage of patients reporting postoperative dysphagia may be underestimated by the findings of this study, because elderly patients are more likely to have dysphagia than are younger patients. It is also possible that the increased rate of radiographic recurrence in younger patients is reflective of the higher rate of availability of follow-up barium esophagography in this group rather than a true increased risk of radiographic recurrence.

Analysis of preoperative symptoms was also limited by the fact that most of these data were derived from retrospective review of existing medical records. Although most patients had clear prospective documentation of the presence or absence of symptoms such as reflux, regurgitation, dysphagia, and shortness of breath, other symptoms, such as cough and hoarseness, were less well documented. Such important postoperative symptoms as early satiety, diarrhea, and excessive flatulence were rarely assessed preoperatively. These symptoms can be the source of long-term patient dissatisfaction and warrant further study.

Summary

In the largest series to date, we found that laparoscopic repair of GPEH is technically feasible, is associated with good to excellent outcomes in close to 90% of patients, and carries low morbidity and mortality in the hands of experienced surgeons. Patients who are obese, who are older, and who have a greater burden of comorbid illness are at higher risk for adverse postoperative outcomes, but most of these patients can still undergo laparoscopic repair with good results. Decisions regarding esophageal lengthening and mesh cruroplasty are best made at the time of operation on the basis of the specific anatomic considerations of the individual patient. Laparoscopic repair of GPEH provides excellent patient satisfaction and symptom resolution, with reoperation rates that are comparable to those of the best open series.[10,25]

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Discussion

Dr Toni Lerut *(Leuven, Belgium).* It is a privilege for me to discuss this excellent and important presentation reporting an in-depth study on the results of what is now by far the largest series on repairs of GPEH. The conclusion is that laparoscopic repair provides excellent patient satisfaction and symptom resolution, with reoperation rates comparable to those of the best open series. Despite your obvious enthusiasm, Dr Luketich, I do have some concerns and questions.

This surgery remains to be considered as a complex and major surgery, with duration of intervention, major complication rates, and mortality figures equaling those now obtained for esophagectomy in centers of excellence, in fact 1.4% for your own center. The overall reintervention rate, including reoperation for recurrence, was 8% in this series, whereas recurrence remains as high as 15%. Although patient satisfaction reached 90%, a detailed analysis of your data indicates that postoperative symptoms such as dysphagia, heartburn, and bloating are recurring in about 1 in 4 cases, and the need for proton pump inhibitor continuation is as high as 40%. So to me it appears that we are not yet there. I have 3 questions.

First, your 30-day mortality was 1.7%, but overall 85 patients died during follow-up. Because half of the patients in your series were older than 70 years or had a CCI score of 3 or more, what were the 6-month and 1-year mortalities, which in fact reflect much more better the true postoperative mortality?

Second, Stylopoulos and Rattner in 2002, with a Markov Monte Carlo decision analytic model, calculated that for the many patients with minor symptoms, such as heartburn, bloating, and so on, a policy of watchful waiting entails a lifetime risk of development of acute symptoms requiring surgery estimated at 1.1% per year, with mortality related to emergency surgery of 5.4%. So they calculated an overall lifetime risk of dying of paraesophageal hernia in a patient managed by watchful waiting to be 1%, which is less than the 30-day mortality in your series. Given these data, and given the high comorbidity in your population, your median age of 70 years, the substantial postoperative complications and readmission rate, and the 8% mortality rate among patients older than 80 years, what according to your experience are now the guidelines for this subset of patients?

Dr Luketich. Could you just summarize that second question? I didn't quite hear the question at the end.

Dr Lerut. Given Rattner's data and the high comorbidity in your population, your median age of 70 years, your high readmission and complication rate, and the high postoperative mortality in patients older than 80 years, what are your guidelines for this subset of patients?

Dr Luketich. Guidelines for entry for elective repair?

Dr Lerut. Exactly.

Dr Luketich. I see.

Dr Lerut. Finally, the recurrence rate was 15%. Could you tell us whether in this subset of patients you performed with time subsequent barium esophagography? If so, did this show further progression of the size of such intrathoracic migration, particularly in the group of younger patients who seem to be more at risk for recurrence simply by virtue of surviving longer than the elderly group? What is the scheme, the algorithm, for follow-up in those cases?

Dr Luketich. Thank you, Dr Lerut. To the first question, the mortalities at 6 months and 1 year, I can't give you those data. We looked primarily at 30-day mortality. Certainly in looking at this group of elderly patients, there are obviously natural deaths occurring in significant numbers among these patients with time. What we did find was that if the CCI score was low and the patient was younger than 70 years, or even older than 70 years with a low CCI score, the 30-day mortality was nil. I hope that answers that question. We do have the data to look more closely at exactly which patients died of at 6 months and 1 year, but it was clear that these deaths did not appear to be related to the operation.

I'll answer the last question next, because I am not sure I understand or can answer the second question. Looking at those small radiographic recurrences, no doubt they are a significant concern. If we try and repair a hiatal hernia, an incisional hernia, or a groin hernia and have any type of hernia recurrence, we are always concerned that it is going to lead to a larger recurrence, then potential symptoms, and then reoperation. I can tell you that when we looked at that first subset of patients back in 2000, when Andrew Pierre presented those data, we had a reoperative rate of around 2%. Those patients have a follow-up now of 77 months, with a reoperation rate up to 4%. I think that may be where the rate is peaking. That is what it looks like to us; most of the recurrences that require reoperation are within 2 to 3 years. Once we get beyond that, we seem to see very few. There will be some, I am certain, and we have seen a few, but not many. And even in this article, when you look at the early data compared to the late data, it does appear that there is some stability of that radiographic recurrence.

In looking back at the laparoscopic randomized trial that was presented at the American Surgical Society meeting a couple of years ago, those were 6-month data showing 9% radiographic

recurrence in the mesh arm and 24% without mesh. The follow-up data have not been presented on that, but it will be interesting to see how many of those recurrences become symptomatic and how many require reoperation with mesh. We have tried to present that, most recently at the Digestive Disease Week, with our 77-month follow-up, as I mentioned.

In terms of establishing better guidelines for elective repair and looking at the likelihood of significant symptoms and whether these patients should undergo surgery or maybe would best be considered for medical treatment, a variety of indexes have been proposed to address this question. In our clinics, what we are seeing is primarily referral for symptoms, for specific problems, whether anemia, dysphagia, pain, heartburn, or whatever. Although there is no doubt that some of those patients still have symptoms after the surgery, what isn't known or is difficult to assess is the level of the symptoms. That is, results are less meaningful if you look merely at presence or absence of dysphagia, versus an index of occasional problems with hard solids. A significant number of the patients fall into that category; they are eating a regular diet but have occasional dysphagia with hard solids. I think part of that is related to the Collis gastroplasty. It does lead to a small segment of relatively amotile neoesophagus, and that can dilate with time. No doubt, the Collis gastroplasty carries some significant limitations. In lieu of getting that tension-free segment of intra-abdominal esophagus, however, it is probably the best approach to that group of patients short of further esophageal mobilization. We have not really changed our guidelines, but we are trying now to evaluate those symptoms more closely, because it is clear that some of them are present. All decrease significantly with time. And the one thing that is important to look at is the final analysis of surgical satisfaction and the final analysis of the GERD-HRQoL score being 90% improved.

So we don't have the answer to some of those questions. I can tell you that we are looking at the issue and trying to study it more carefully. We have established detailed questionnaires, and it takes significant amounts of time and money to follow each of these questions carefully with time and try to assign a score, rather than a yes or no. Most of these patients do seem very satisfied, very happy, even when they come to the postoperative clinics with some of these symptoms present.

APPENDIX E1. Details of Surgical Technique

In 2003, the approach switched from a hand-over-hand technique[1,2] to an approach that begins with complete reduction of the hernia sac. The hernia sac is grasped just inside the diaphragmatic crura at the 12 o'clock position, and the lining of the sac is everted and incised with ultrasonic dissection, allowing access to the areolar attachments of the hernia sac to mediastinal structures. Dissection in this plane is associated with little blood loss and easy visualization of the bilateral pleura, esophagus, and vagus nerves and reduces the entire hernia sac into the abdomen, thereby returning the stomach to its anatomic position.

As the reduction is completed, the sac is incised just inside the crura, with care taken to preserve the crural peritoneal lining. Esophageal mobilization within the mediastinum is routinely performed to at least the level of the inferior pulmonary veins. Anterior and posterior vagus nerves are identified and preserved. Short gastric vessels are divided and the gastric fat pad mobilized to allow visualization of the gastroesophageal junction, and the intra-abdominal location of the gastroesophageal junction in a neutral resting position in the abdomen is assessed. Dissection continues until a minimum of 2 cm of tension-free intra-abdominal esophagus is present. If further mobilization fails to produce a tension-free segment of intra-abdominal esophagus, we perform an esophageal lengthening procedure. Initially, we used the end-to-end anastomosis technique.[1] As we gained experience, we converted to doing stapled wedge gastroplasty, as described by Whitson and colleagues,[8] because of the ease of performing the technical steps and the greater reproducibility in resident teaching than with the end-to-end anastomosis technique. An antireflux procedure (a floppy Nissen fundoplication in most cases) is routinely performed. The crura are then reapproximated without tension with nonabsorbable 0 suture. If the crura are denuded of overlying peritoneum, are unable to hold sutures because of significant attenuation, or cannot be reapproximated without tension, mesh reinforcement with bioprosthetic mesh is performed.

In some cases of very poor esophageal motility, extremes of age, signs of clinical instability (such as intraoperative desaturations or blood pressure instability despite the usual corrective measures), or extreme technical problems, the surgeon may elect intraoperatively to perform an extended gastropexy. When this is chosen, complete hernia sac dissection and crural reapproximation are still performed. Gastropexy is performed from the greater curve of the stomach to the left crus and continued along the anterior abdominal wall toward the umbilicus. A gastrostomy tube is placed along this gastropexy line to secure further the intra-abdominal location of the stomach.